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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,505	02/08/2007	Steven Sedgwick	015959-00015	9806

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EXAMINER

KIM, ALEXANDER D

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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04/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No. 10/588,505	Applicant(s) SEDGWICK ET AL.	
	Examiner ALEXANDER D. KIM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Claims 1-40 are pending in the instant application.

Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a Ltet protein.
- II. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a Bfal protein.
- III. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a Bub2 protein.
- IV. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a CDCS protein.
- V. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a CDC15 protein.

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- VI. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a CDC28 protein.
- VII. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a Tp12 protein.
- VIII. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a ASRS virus Nsp13 protein.
- IX. Claim 40, drawn to a vector or a cell wherein the heterologous gene encodes a mRNA Cap 1 methy transferase protein.
- X. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is Ltet protein.
- XI. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a Bfal protein.
- XII. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a Bub2 protein.
- XIII. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a CDCS protein.
- XIV. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a CDC15 protein.
- XV. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a CDC28 protein.

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- XVI. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a Tp12 protein.
- XVII. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a ASRS virus Nsp13 protein.
- XVIII. Claim 40, drawn to a method for purifying a heterologous protein wherein the heterologous protein is a mRNA Cap 1 methy transferase protein.
- XIX. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a Ltel protein.
- XX. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a Bfal protein.
- XXI. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a Bub2 protein.
- XXII. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a CDCS protein.
- XXIII. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a CDC15 protein.
- XXIV. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a CDC28 protein.
- XXV. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a Tp12 protein.

XXVI. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a ASRS virus Nsp13 protein.

XXVII. Claim 40, drawn to a method for preparing a cell wherein the heterologous gene encodes a mRNA Cap 1 methy transferase protein.

The inventions listed as Groups I-XXVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are linked by the technical feature of a cell that expresses both chromosomal genes and extra-chromosomal genes, wherein (a) the expressed extra-chromosomal genes include a gene with an essential function, the expression of which is unconditionally required for survival of the cell, (b) the expressed chromosomal genes do not provide that essential function, and (c) the extra-chromosomal genes include a heterologous gene, the expression of which is controlled by a promoter that is functional in the cell and wherein the extra-chromosomal genes are located on an extra-chromosomal vector. However this technical feature is not special because it does not constitute an advance over the prior art. Murphy et al. (Gene, 1995, Vol. 155, pages 1-7, cited in the IDS filed on 08/04/2006) teaches E. coli cell having null alleles of essential gene secE which were complemented for its function by a wild-type (wt) copy expressed from a plasmid (i.e., extra-chromosomal genes as shown in the Fig. 1 on page 2) which meets the limitation of Claim 1 (a and b). The plasmid of Murphy et al. also contains Km^R which meets the limitation of heterologous gene in the extra-

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chromosomal genes (i.e., plasmid); thus, meeting the limitation of Claim 1 (c). Because the special technical features of Groups I-XXVII lack novelty or inventive step, and the technical features are not contributions over the prior art.

3. The claims will be examined only to the extent they read on the elected subject matter.

Claims 1-4, 7-9, 10-17, 19-39 link Group I to IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 7-9, 10-17, 19-39.

Claims 5-6 and 19-39 link Group X to XVIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 4-6 and 19-39.

Claims 18 and 19-39 link Group XIX to XXVII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 18 and 19-39.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims

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that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election of Species

4. Claim 7 in Groups I to IX is generic to the following disclosed patentably distinct species of the essential gene (i.e., MOB1, Cdc33 and Hsp10) because each gene has distinct structure having different nucleotide sequence and different keywords search against database. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. For example, each essential gene have distinct chemical structure by virtue of distinct amino acid sequence. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not

patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652